

DEPARTMENT OF FOOD AND AGRICULTURE

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing is scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department of Food and Agriculture (Department) no later than 15 days prior to the close of the written comment period.

Subject Matter of Proposed Regulations: Ovine Brucellosis

Sections Affected: Amend section 760.4, amend the heading of Article 3.5, and adopt section 765.

Specific Purpose of Each Adoption, Amendment, or Repeal

Food and Agricultural Code section 9561 authorizes the State Veterinarian of the Department to establish regulations to prevent or eradicate any condition that could cause risk to animals or the health and safety of the citizens of this state. Section 9562 further authorizes the State Veterinarian to quarantine or restrict the movement of animals or animal products to minimize the risk of an illness that could kill or seriously damage other animals or humans. Section 9570 authorizes the State Veterinarian to restrict the importation of animals, animal products, or other property from any state, territory, or foreign country should a quarantine be invoked pursuant to section 9562.

In compliance with sections 9561, 9562 and 9570, the Department has in place existing ovine brucellosis disease control regulations under Article 3 (Interstate and Intrastate Movement of Sheep and Goats) of Chapter 2, Division 2, of Title 3 of the California Code of Regulations.

This proposal amends section 760.4 of Article 3 (Interstate and Intrastate Movement of Sheep and Goats), which is needed to further strengthen California's requirements for the importation of sheep by requiring additional testing of animals potentially having ovine brucellosis. The Department is also deleting a requirement that is no longer necessary in section 760.4(a)(2)(B) that rams used for breeding prior to returning to California must comply with the testing requirements of subsection (a)(2).

This proposal also amends the heading of Article 3.5 (*Brucella ovis* Free Flock Certification), and adopts new section 765 of Article 3.5. This adoption would establish a voluntary certification for owners of sheep choosing to incorporate production practices acknowledged by the Department as efforts to control the spread of and maintain a flock of sheep free of brucellosis ovis. Designating California flocks as *Brucella ovis* Free has the potential to increase marketability of California sheep both nationally and worldwide. *Brucella ovis* Free Flock Certification comes at the request of the California Wool Growers Association, which represents the sheep and lamb producers or owners of California, and is supported by the California Farm Bureau Federation.

The overall intent of these regulation changes is to prevent and control the spread of ovine brucellosis in California and the United States pursuant to Food and Agricultural Code section 9561.

Factual Basis

The Department is responsible for promoting and protecting the agricultural industry of California. Further, the Department seeks to enhance, protect and perpetuate the ability of the agricultural industry to produce food and fiber in a way that benefits the general welfare and economy of California, and maintains the economic well-being of agriculturally dependent rural communities in California pursuant to Food and Agricultural Code sections 401 and 401.5.

The Department's Animal Health Branch is the state's organized, professional veterinary medical unit that protects livestock populations, consumers, and California's economy from catastrophic animal diseases and other health or agricultural problems. The Branch addresses diseases and other problems that cannot be successfully controlled on an individual animal or herd basis, but require statewide coordinated resources.

Pursuant to Food and Agricultural Code sections 9561, 9562, and 9570, the Animal Health Branch has in place regulations establishing the requirements for Interstate and Intrastate Movement of Sheep and Goats under Article 3 of Chapter 2, Division 2, of Title 3 of the California Code of Regulations. The requirements are in place to control or eradicate the spread of diseases that could potentially cause a threat to human and animal health and safety. This proposal amends the existing interstate movement requirements for a disease of sheep known as brucellosis ovis.

Ovine brucellosis is a disease caused by the organism *Brucella ovis* and is primarily a genital disease of rams (male sheep). Clinical disease occurs less often in ewes (female sheep) but ewes are thought to play a significant role in natural transmission between rams. The disease manifests as poor fertility due to a lowered rate of conception and aborted, weak or nonviable lambs. Because of the transient nature of the infection in ewes, control measures are directed at the rams.

The diagnosis of *Brucella ovis* is made through palpation, semen examination, or a blood test. Antibiotics and vaccines may be used in some countries to treat or vaccinate infected ewes, however, there is no effective treatment for infected rams. The only safe way to control the disease is to remove infected rams from the herd and prevent the introduction of new infection by only accepting rams from flocks free of the disease, or by having rams blood tested negative for the disease.

Ovine brucellosis exists in many other countries, including Australia, New Zealand, South Africa and Europe. In the United States, states such as Colorado, Washington, Wyoming, and Montana have interstate movement requirements specifying that rams must be negative tested for *Brucella ovis* or be from a *Brucella ovis* free flock before they are allowed entry into the state.

Currently, California requires rams to have identification, a Certificate of Veterinary Inspection, and a negative official test for *Brucella ovis* before authorized importation to California. The Department has determined that these requirements may not sufficiently prevent the importation of *Brucella ovis* infected rams from entering the state, does not provide for the retesting of positive animals, or address testing requirements for animals originating from flocks in which the disease has been diagnosed. This proposal will strengthen the existing importation requirements where weaknesses exist and provide for alternatives where testing procedures may be flawed or when disease no longer exists.

This proposal also establishes a voluntary certification process for sheep owners choosing to adopt production practices recognized by the Department as protecting sheep health and increasing awareness of ovine brucellosis. Flocks in compliance with the Department's voluntary plan may be recognized by the Department as a *Brucella ovis* Free Flock. The certification process comes at the request and recommendation of California's sheep industry (California Wool Grower's Association), and is supported the California Farm Bureau Federation. Flocks certified as a *Brucella ovis* Free Flock will be able to move interstate without additional testing for brucellosis ovis, and potentially have more access to international markets.

In order to preserve livestock health and to promote California's sheep industry, the Department proposes the following regulations pertaining to brucellosis ovis:

1) Amend section 760.4 Ovine Brucellosis – Requirements for Entry of Rams into California.

The Department is amending the pre-entry *Brucella ovis* testing requirements for rams entering the state in an effort to prevent the introduction and spread of this disease in California sheep.

Existing subsection (a)(2)(B) deletes the requirement that rams used for breeding prior to returning to California must comply with the testing requirements of subsection (a)(2). The Department has determined this requirement is no longer needed as most rams going to a show outside of California would not generally be used for breeding before returning to the State. Additionally, given that the livestock shows generally last one or two weeks maximum, any ram used for breeding and becoming infected, would not show a positive reading to a test in such a short amount of time before returning to California. Therefore, the Department believes this requirement is no longer justifiable and should be stricken.

Proposed subsection (a)(2)(B) specifies additional testing requirements for animals that have a suspicious or positive outcome on an initial test. This retest requirement will help to clarify whether or not an animal is indeed infected with the disease. The Department believes this second test is necessary because the test used for detecting *Brucella ovis* does not indicate that an animal is positive or negative. Instead, test results are read on a continuous scale as suspicious, and can either be more positive or negative, but not definitively either. Therefore, to ensure an animal in all likelihood is infected, the Department is requiring a second test to confirm or negate the initial test. In order for the animal to be allowed entry into the State, results of the retest must fall within the negative category. Negative test results are necessary to verify that animals are not infected

carriers of disease. Requiring that animals be tested within 30-60-days after the initial suspicious or positive test is an industry standard, as it has proven to be the necessary additional length of time to allow any exposure to disease to develop into a suspicious or positive reading on a test for the disease.

The adoption of subsections (b)(1) and (2) adds a second test for rams originating from a flock where the disease has been identified within the past 12 months. The Department believes this second or follow-up test is necessary to identify diseased animals that may not have been detected on the initial test. The 45-120-day retest period is an industry standard and adequate amount of time for an animal that may have been exposed to disease to have a suspicious or positive reading on a test result. If the disease has existed in the flock within the last year, the existence or reoccurrence of disease is a possibility. Therefore, the Department believes a retest is necessary to prevent this possibility of disease exposure and outbreak.

Additionally, the Department is making nonsubstantive changes to section 760.4 by italicizing the organism "*Brucella ovis*" where appropriate, correcting a misspelled word, and renumbering for organizational purposes.

2) Amend heading of Article 3.5 *Brucella ovis* Free Flock Certification.

The Department is amending the heading of Article 3.5 to clarify that the article pertains to the voluntary certification of *Brucella ovis* Free Flocks in California. Amending the heading will make the requirements easier to find for persons choosing to certify a flock or interested in the process. The intent of Article 3 and Article 3.5 are the same, to prevent the spread and introduction of brucellosis ovis into California flocks, however, the means of attaining these goals are distinctly separate, as described below.

(3) Adopt section 765. *Brucella ovis* Free Flock Certification Requirements.

The interstate movement requirements in section 760.4 of Article 3, are imposed upon any person outside of California importing sheep into California. The requirements are based upon compliance with general federal interstate transportation regulations found under various sections of 9 CFR Ch. I (2005). The Department's regulations require a Certificate of Veterinary Inspection and include additional, yet standard, testing requirements with leniency for flocks certified to be free of brucellosis ovis from their state of origin.

Proposed section 765 of Article 3.5 is intended solely for flocks of sheep originating or raised in California that could be marketed to other states or foreign countries. Section 765 is intended to decrease stringent testing requirements currently imposed on California sheep owners by establishing a voluntary certification process. This process will require the adoption of production practices recognized by the Department as protecting sheep health and increasing awareness of ovine brucellosis. Flocks in compliance with the Department's voluntary plan will be recognized by the Department as a *Brucella ovis* Free Flock.

Currently, when California sheep or flocks move interstate, they are held to a high degree of testing requirements because California does not have a *Brucella ovis* Free Flock

Certification process. *Brucella ovis* Free Flock Certification exists in Missouri, Kansas, South Dakota, Montana, and Idaho. When a flock of sheep or individual sheep are moved into California from a certified free flock from one of these states, they are not considered to be at high-risk for carrying the disease, and therefore allowed entry into California with minimal testing. Therefore, the Department is establishing its own voluntary certification process consistent with these states. The voluntary certification process also comes at the request of the California Wool Grower's Association, and is supported by the California Farm Bureau Federation. The certification process is a means of promoting flocks and individual sheep originating or raised in California, in addition to preventing the spread and introduction of disease.

Section 765(a) incorporates by reference definitions used in Article 3, Interstate and Intrastate Movement of Sheep and Goats, section 760, Definitions. The Department is choosing to make this incorporation to avoid unnecessary duplication of the same terms.

Subsection (b) specifies information regarding *Brucella ovis* Free Flock Certification may be obtained from any Animal Health Branch District Office. The Department's Animal Health Branch is organized into four strategically located district offices. Each district office is a central point of contact for the public and veterinarians located within that region regarding livestock and poultry disease surveillance and eradication. As with other Department supported certification procedures (e.g., Bovine Brucellosis Certified Free Herd Certification, Bovine Tuberculosis Accredited Free Herd Certification), the local Animal Health Branch District Office should be the first point of contact for persons interested in obtaining certification. Contact information for each district office is not included in this proposal as the information is widely available by contacting the Department's Animal Health Branch Headquarters Office in Sacramento, in any city telephone directory under the government listings section, through any private veterinary practitioners' office, and via the Internet.

Subsection (c) sets forth the requirements for establishing a flock of sheep as *Brucella ovis* free. A flock of sheep may be certified as free of brucellosis ovis when all rams six (6) months of age and older have two (2) negative tests conducted 45-120 days apart. This age and testing timeframes are industry standards and proven scientifically to be the best time for identifying disease-infected animals. These testing requirements are more stringent than the interstate movement requirements as specified in section 760.4 because the Department is representing these animals as free of disease and must hold them to the highest degree of science-based testing standards.

Subsection (d) specifies that the Department will provide written verification to the owner of the flock when all required testing is complete. The Department will accept test results directly from the laboratory or the veterinarian who conducted the testing. The Department will send written confirmation to the owner verifying the flock has met the Department's requirements for *Brucella ovis* Free Flock Certification.

Subsection (e) specifies the requirements of the *Brucella ovis* test. The testing of samples must be performed in a laboratory approved by the Department to ensure proper handling of specimens and testing procedures. Samples must also be taken from the animal by a licensed, accredited veterinarian, who has been educated and properly trained to take

samples, handle specimens, and manage livestock. The Department is also requiring tests used to certify *Brucella ovis* free flocks are approved by the Department to ensure consistent science-based and industry accepted testing standards are used.

Subsection (f) specifies the requirements for maintaining a flock of sheep as a *Brucella ovis* Free Flock. The Department is proposing certification be maintained on an annual basis, beginning the date written confirmation identifies the flock as a *Brucella ovis* Free Flock. The Department is not proposing an annual renewal process, however in order for a flock to maintain its continuous free flock certification status a minimum testing schedule must be maintained by the owner.

Subsection (f)(1) specifically identifies testing protocol necessary for a flock to maintain continuous free flock status. The Department is requiring all test eligible rams within the flock (6 months of age and older) to have a negative test for *Brucella ovis* once every nine to fifteen month period. Annual testing helps to ensure the disease has not been overlooked by prior testing procedures, is consistent with other certification procedures, and is supported by the sheep industry.

In subsection (f)(2), the Department is proposing that when a new ram is brought into the flock, the animal must be from an already *Brucella ovis* free flock in California or be from a flock certified as free of *Brucella ovis* by another state's animal health agency, or be isolated from the flock until the animal has two negative tests conducted 45-120 days apart. Again, the 45-120 day retest period is an industry standard and an adequate amount of time for an animal that may have been exposed to disease to have a suspicious or positive reading on a test result.

Subsection (f)(3) states any flock losing its free status can only regain free status by repeating the certification process. Requirements for certification as stated in proposed subsection (c) require all rams six (6) months of age and older complete two (2) negative tests 45-120 days apart.

Subsection (g) requires any ram testing positive for *Brucella ovis* be isolated from all other sheep and have a retest conducted to confirm, or negate, the initial positive test. Any positive ram left to commingle with the remainder of the flock will result in the flock losing the certified free status. This provision is needed to be sure no infected sheep are imported into or allowed to commingle with a certified free flock. This subsection also gives the owner the option to remove the suspicious sheep from the flock rather than retest the animal(s). This option is made available should the owner have multiple initially positive animals requiring a second test.

Underlying Data

California Wool Growers Association letter dated June 21, 2005 requesting the Department to develop a voluntary testing process to certify flocks as *Brucella ovis* Free.

California Farm Bureau Federation letter dated July 25, 2005 supporting the development of a plan for voluntary *Brucella ovis* Flock Certification.

Business Impact

The Department has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. The following compliance requirements are projected to result from the proposed action:

- 1) Paperwork: This proposal contains paperwork requirements consisting of laboratory testing for *Brucella ovis* in rams. The potential costs would be for the testing or retesting for *Brucella ovis* in rams entering the state, and for the testing of rams in flocks whose owners choose to certify the flock as *Brucella ovis* Free, as specified in this proposal. The testing requirements are intended to control and possibly prevent a disease of sheep that will benefit California's sheep industry, promote healthy animals, and make the industry's products marketable both nationally and internationally.
- 2) Record Keeping: This proposal does not contain a record keeping requirement. However, for a person or business participating in the certification process in California, the written certification issued by the Department could be considered a record. The certification is valid for one year as specified in this proposal.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment; however, the livestock industry or veterinary medical practices may require specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department of Food and Agriculture would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed regulation.